Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

--Claim 1. (Currently amended) A process for preparing a multivesicular liposomal particle composition, the process comprising:

a) pre-sterilizing all composition ingredients;

[[a]] b) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

[[b]] c) mixing and emulsifying said first emulsion and a second aqueous phase ~~in a mixer with an energy input~~ to provide a second emulsion, said second emulsion comprising a continuous aqueous phase;

[[c]] d) removing the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles ~~of pre-determined size relative to energy input~~ of pre-determined, uniform size distribution; and

[[d]] e) ~~filtering~~ adjusting the concentration of the multivesicular liposomal particle composition by cross-flow filtration,

wherein all steps are carried out under aseptic conditions~~, and wherein all solutions are sterile filtered prior to use, and wherein the multivesicular liposomal particle composition is immediately suitable for administration into humans~~.

Claim 2. (Currently amended) The process of claim 1, wherein at least one mixing step is carried out in a dynamic or static mixer.--

Claims 3-10. (Original)

Claim 11. (Canceled)

Claim 12. (Previously presented)

Claim 13. (Original)

Claims 14-16. (Previously presented)

Claims 17-19. (Original)

Claims 20-22. (Previously presented)

Claim 23. (Original)

Claim 24. (Previously presented)

Claims 25-27. (Original)

Claims 28-32. (Previously presented)

Claims 33-35. (Original)

Claims 36-47. (Canceled)

Claim 48. (Canceled)

--Claim 49. (Currently amended) A process for preparing a multivesicular liposomal particle composition, the process comprising:

a) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

b) mixing and emulsifying said first emulsion and a second aqueous phase ~~in a mixer with an energy input~~ to provide a second emulsion, said second emulsion comprising a continuous aqueous phase;

c) removing the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles ~~of pre-determined size relative to energy input~~ of pre-determined, uniform size distribution; ~~and~~

d) ~~filtering~~ adjusting the concentration of the multivesicular liposomal particle composition by cross-flow filtration[[,]] ; and

e) sterilizing the multivesicular liposomal particle composition.

wherein all steps are carried out under aseptic conditions~~, and wherein all solutions are sterile filtered prior to use, and wherein the multivesicular liposomal particle composition is immediately suitable for administration into humans~~.--

Claim 50. (Canceled)

Claim 51. (Original)

Claims 52-62. (Previously presented)

--Claim 63. (New) A process for preparing a multivesicular liposomal particle composition, the process comprising:

a) pre-sterilizing all composition ingredients;

b) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

c) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion, said second emulsion comprising a continuous aqueous phase;

d) removing the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles of pre-determined, uniform size distribution; and

e) exchanging buffer in the multivesicular liposomal particle composition by cross-flow filtration,

wherein all steps are carried out under aseptic conditions.

Claim 64. (New) A process for preparing a multivesicular liposomal particle composition, the process comprising:

a) pre-sterilizing all composition ingredients;

b) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

c) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion, said second emulsion comprising a continuous aqueous phase;

d) removing the volatile water-immiscible solvent from the second emulsion to form a composition of drug-containing multivesicular liposomal particles of pre-determined, uniform size distribution; and

e) removing unencapsulated drug in the multivesicular liposomal particle composition by cross-flow filtration,

wherein all steps are carried out under aseptic conditions.

Claim 65. (New) A process for preparing a multivesicular liposomal particle composition, the process comprising:

a) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

b) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion, said second emulsion comprising a continuous aqueous phase;

c) removing the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles of pre-determined, uniform size distribution;

d) exchanging buffer in the multivesicular liposomal particle composition by cross-flow filtration; and

e) sterilizing the multivesicular liposomal particle composition,

wherein all steps are carried out under aseptic conditions.

Claim 66. (New) A process for preparing a multivesicular liposomal particle composition, the process comprising:

a) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

b) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion, said second emulsion comprising a continuous aqueous phase;

c) removing the volatile water-immiscible solvent from the second emulsion to form a composition of drug-containing multivesicular liposomal particles of pre-determined, uniform size distribution;

d) removing unencapsulated drug in the multivesicular liposomal particle composition by cross-flow filtration; and

e) sterilizing the multivesicular liposomal particle composition,

wherein all steps are carried out under aseptic conditions.

Claim 67. (New) A process for preparing a multivesicular liposomal particle composition, the process comprising:

a) pre-sterilizing all composition ingredients;

b) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

c) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion, said second emulsion comprising a continuous aqueous phase;

d) removing the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles of pre-determined, uniform size distribution; and

e) filtering the multivesicular liposomal particle composition by cross-flow filtration to adjust the concentration,

wherein all steps are carried out under aseptic conditions.

Claim 68. (New) A process for preparing a multivesicular liposomal particle composition, the process comprising:

a) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

b) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion, said second emulsion comprising a continuous aqueous phase;

c) removing the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles of pre-determined, uniform size distribution;

d) filtering the multivesicular liposomal particle composition by cross-flow filtration to adjust concentration; and

e) sterilizing the multivesicular liposomal particle composition,

wherein all steps are carried out under aseptic conditions.

Claim 69. (New) A process for preparing a multivesicular liposomal particle composition, the process comprising:

a) pre-sterilizing all composition ingredients;

b) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

c) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion, said second emulsion comprising a continuous aqueous phase;

d) removing the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles of pre-determined, uniform size distribution; and

e) filtering the multivesicular liposomal particle composition by cross-flow filtration to exchange buffer therein,

wherein all steps are carried out under aseptic conditions.

Claim 70. (New) A process for preparing a multivesicular liposomal particle composition, the process comprising:

a) pre-sterilizing all composition ingredients;

b) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

c) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion, said second emulsion comprising a continuous aqueous phase;

d) removing the volatile water-immiscible solvent from the second emulsion to form a composition of drug-containing multivesicular liposomal particles of pre-determined, uniform size distribution; and

e) filtering the multivesicular liposomal particle composition by cross-flow filtration to remover unencapsulated drug therein,

wherein all steps are carried out under aseptic conditions.

Claim 71. (New) A process for preparing a multivesicular liposomal particle composition, the process comprising:

a) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

b) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion, said second emulsion comprising a continuous aqueous phase;

c) removing the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles of pre-determined, uniform size distribution;

d) filtering the multivesicular liposomal particle composition by cross-flow filtration to exchange buffer; and

e) sterilizing the multivesicular liposomal particle composition,

wherein all steps are carried out under aseptic conditions.

Claim 72. (New) A process for preparing a multivesicular liposomal particle composition, the process comprising:

a) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

b) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion, said second emulsion comprising a continuous aqueous phase;

c) removing the volatile water-immiscible solvent from the second emulsion to form a composition of drug-containing multivesicular liposomal particles of pre-determined, uniform size distribution;

d) filtering the multivesicular liposomal particle composition by cross-flow filtration to remove unencapsulated drug; and

e) sterilizing the multivesicular liposomal particle composition,

wherein all steps are carried out under aseptic conditions.

Claim 73. (New) The process of any of claims 1, 63, 64, 67, 69 or 70 wherein pre-sterilization of all composition ingredients is conducted by filtration through a filter having pores at least as small as 0.22 μm.

Claim 74. (New) A method for increasing the yield of a process for making a multivesicular liposomal composition, the method comprising:

a) pre-sterilizing all composition ingredients;

b) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

c) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion, said second emulsion comprising a continuous aqueous phase;

d) removing the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles of pre-determined, uniform size distribution; and

e) adjusting the concentration of the multivesicular liposomal particle composition by cross-flow filtration,
wherein all steps are carried out under aseptic conditions.

Claim 75. (New) A method for increasing the yield of a process for making a multivesicular liposomal composition, the method comprising:

a) pre-sterilizing all composition ingredients;

b) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

c) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion, said second emulsion comprising a continuous aqueous phase;

d) removing the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles of pre-determined, uniform size distribution; and

e) exchanging the buffer of the multivesicular liposomal particle composition by cross-flow filtration,
wherein all steps are carried out under aseptic conditions.

Claim 76. (New) A method for increasing the yield of a process for making a multivesicular liposomal composition, the method comprising:

a) pre-sterilizing all composition ingredients;

b) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

c) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion, said second emulsion comprising a continuous aqueous phase;

d) removing the volatile water-immiscible solvent from the second emulsion to form a composition of drug-containing multivesicular liposomal particles of pre-determined, uniform size distribution; and

e) removing unencapsulated drug in the multivesicular liposomal particle composition by cross-flow filtration,

wherein all steps are carried out under aseptic conditions.

Claim 77. (New) A method for increasing the yield of a process for making a multivesicular liposomal composition, the method comprising:

a) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

b) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion, said second emulsion comprising a continuous aqueous phase;

c) removing the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles of pre-determined, uniform size distribution;

d) adjusting the concentration of the multivesicular liposomal particle composition by cross-flow filtration; and

e) sterilizing the multivesicular liposomal particle composition,

wherein all steps are carried out under aseptic conditions.

Claim 78. (New) A method for increasing the yield of a process for making a multivesicular liposomal composition, the method comprising:

a) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

b) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion, said second emulsion comprising a continuous aqueous phase;

c) removing the volatile water-immiscible solvent from the second emulsion to form a composition of multivesicular liposomal particles of pre-determined, uniform size distribution;

d) exchanging buffer in the multivesicular liposomal particle composition by cross-flow filtration; and

e) sterilizing the multivesicular liposomal particle composition,

wherein all steps are carried out under aseptic conditions.

Claim 79. (New) A method for increasing the yield of a process for making a multivesicular liposomal composition, the method comprising:

a) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

b) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion, said second emulsion comprising a continuous aqueous phase;

c) removing the volatile water-immiscible solvent from the second emulsion to form a composition of drug-containing multivesicular liposomal particles of pre-determined, uniform size distribution;

d) removing unencapsulated drug in the multivesicular liposomal particle composition by cross-flow filtration; and

e) sterilizing the multivesicular liposomal particle composition,

wherein all steps are carried out under aseptic conditions.

Claim 80. (New) A method for increasing the yield of a process for making a multivesicular liposomal particle composition, the process comprising:

a) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

b) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion, said second emulsion comprising a continuous aqueous phase;

c) removing the volatile water-immiscible solvent from the second emulsion to form a composition of drug-containing multivesicular liposomal particles of pre-determined, uniform size distribution;

d) filtering the multivesicular liposomal particle composition by cross-flow filtration to perform at least one process selected from the group consisting of concentration adjustment, buffer exchange and removal of unencapsulated drug; and

e) sterilizing the multivesicular liposomal particle composition,

wherein all steps are carried out under aseptic conditions.

Claim 81. (New) A method for increasing the yield of a process for making a multivesicular liposomal particle composition, the process comprising:

a) pre-sterilizing all composition ingredients;

b) providing a first emulsion by mixing a first aqueous phase and a volatile water-immiscible solvent phase, said solvent phase comprising at least one amphipathic lipid and at least one neutral lipid;

c) mixing and emulsifying said first emulsion and a second aqueous phase to provide a second emulsion, said second emulsion comprising a continuous aqueous phase;

d) removing the volatile water-immiscible solvent from the second emulsion to form a composition of drug-containing multivesicular liposomal particles of pre-determined, uniform size distribution; and

e) filtering the multivesicular liposomal particle composition by cross-flow filtration to perform at least one process selected from the group consisting of concentration adjustment, buffer exchange and removal of unencapsulated drug,

wherein all steps are carried out under aseptic conditions.

Claim 82. (New) A product produced in accordance with the process of claim 1.

Claim 83. (New) A product produced in accordance with the process of claim 49.

Claim 84. (New) In a process for preparing a multivesicular liposomal composition comprising a sterilization step, preparation of first and second emulsion steps, and a solvent removal step, the improvement comprising the further step of cross-flow filtration to adjust concentration.

Claim 85. (New) In a process for preparing a multivesicular liposomal composition comprising a sterilization step, preparation of first and second emulsion steps, and a solvent removal step, the improvement comprising the further step of cross-flow filtration to perform buffer exchange.

Claim 86. (New) In a process for preparing a drug-containing multivesicular liposomal composition comprising a sterilization step, preparation of first and second emulsion steps, and a solvent removal step, the improvement comprising the further step of cross-flow filtration to remove unencapsulated drug.

Claim 87. (New) In a process for preparing a multivesicular liposomal composition comprising a sterilization step, preparation of first and second emulsion steps, and a solvent removal step, the improvement comprising the further step of adjusting concentration by cross-flow filtration.

Claim 88. (New) In a process for preparing a multivesicular liposomal composition comprising a sterilization step, preparation of first and second emulsion steps, and a solvent removal step, the improvement comprising the further step of performing buffer exchange by cross-flow filtration.

Claim 89. (New) In a process for preparing a drug-containing multivesicular liposomal composition comprising a sterilization step, preparation of first and second emulsion steps, and a solvent removal step, the improvement comprising the further step of removing unencapsulated drug by cross-flow filtration.--